

are basing their False Claims Act suit on allegations that the Defendants violated the Medicare anti-kickback statute, they need not identify any specific claims for payment that were submitted to the government for payment. This not only flies in the face of the well-settled rules governing pleading of False Claims Act *qui tam* suits cited in Defendants' initial memorandum, it also violates common sense. In order to allege that Defendants have violated the False Claims Act, there would still have to be some showing that claims were filed, even under the (legally unsupported) lax pleading standards urged by the Relators, not just an assumption that Defendants may have filed such claims.

The Relators have not provided this Court with any decisions from within the third circuit that support this position and have chosen to ignore the holding in U.S. ex rel. Schmidt v. Zimmer, Inc., 2005 WL 1806502 (E.D. Pa. July 29, 2005), where the District Court for the Eastern District of Pennsylvania held that a relator in a *qui tam* action cannot simply allege an illegal scheme, and then hypothesize that false claims must have been submitted, without presenting to the court even one specific actual false claim. Id.

In U.S. ex rel. Barrett v. Columbia/HCA Healthcare Corp., 251 F.Supp.2d 28 (D.D.C. 2003), relators tried a similar strategy. There, the relators alleged a variety of facts which they contended violated the anti-kickback statute. However, they failed to allege any claims for payment related to the allegedly illegal scheme. According to the court: "Relators need to set out the details of the specific scheme and its falsehoods, as well as supply the time, place and content of false representations, and link that scheme to claims for payment made to the United States." Id. at 35. The court therefore concluded that the complaint failed to meet the particularity requirements of Rule 9(b).

The court in U.S. ex rel. Sharp v. Consolidated Medical Transport, Inc., 2001 WL 1035720 (N.D. Ill. 2001) reached a similar conclusion. There, allegations that the defendants had violated the anti-kickback statute were found insufficient to state a claim under the False Claims Act, because the complaint did not allege "facts which suggest that any of the defendants entered into this arrangement for the purpose of obtaining payment of the claims which would otherwise not have been paid had the government known of the scheme." Id. at *11.

Even the cases cited by Relators in their Response involved complaints where at least *some* claims were alleged. In U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F.Supp.2d 1017 (S.D.Tex. 1998), the court found that "Relator has asserted that the explicit certifications of compliance with relevant federal healthcare laws and regulations were false and fraudulent and provided evidence that the government conditioned its approval, payment and Defendant's retention of payment funds on those certifications." Likewise, in U.S. ex rel. Pogue v. American Healthcorp, Inc., 977 F.Supp. 1329 (M.D.Tenn. 1997), the relators at least alleged that the defendant diabetes center filed Medicare and Medicaid reimbursement claims for the treatment of patients who were directed there as a result of allegedly illegal referral arrangements that the center had with the defendant physicians. Id. at 1333. And in U.S. ex rel. McNutt v. Hayleyville Medical Supplies, Inc., 2005 WL 2179164 (11th Cir. 2005), the court stated: "the government has identified as false numerous specific claims the [defendants] made to the federal government."

In the instant case, Relators do not even begin to suggest that there were any specific claims for payment filed by BRMC, let alone that any of those claims were for services provided to patients referred by Drs. Saleh or Vaccaro as the result of the allegedly illegal equipment lease. As the analysis of the Complaint set forth in Defendants' initial Memorandum (pp. 7-8) shows, the

Complaint does not even allege that BRMC actually filed any specific Medicare cost reports, which is the theory on which the whole of Relators' claim rests.²

It is well settled that there is no private right of action under the anti-kickback statute. West Allis Memorial Hospital v. Bowen, 852 F.2d 251, 254-255 (7th Cir. 1988); Donovan v. Rothman, 106 F.Supp.2d 513, 516 (S.D.N.Y. 2000); Barrett, supra, at 37. To allow Relators' Complaint to go forward by simply allowing them to allege that Defendants violated the anti-kickback statute without alleging *any* specific false claims would turn this rule on its head and render it effectively meaningless.

2. Relators Have Failed to Allege Any Violation of the Stark Law

Relators contend that they have sufficiently alleged that an "indirect" financial relationship existed between BRMC and Drs. Saleh and Vaccaro in violation of the Stark law because the rent paid under the equipment lease "otherwise reflects" the volume or value of referrals or other business generated for BRMC by the physicians. However, this was never alleged in the Complaint. Relators simply claimed that the lease was "commercially unreasonable" because BRMC supposedly didn't "need" the equipment and that it was allegedly available for a cheaper price. This falls far short of any specific allegation that the rental payments were reflective of the volume or value of referrals from the physicians, which was not the case since the lease called for fixed monthly payments.

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As pointed out in Defendants' initial Memorandum, BRMC could not have even filed a Medicare cost report seeking payment for services performed while the lease was in effect at the time the Complaint was filed. Contrary to Relators' assertion in footnote 10 of their Response, this is not a matter of fact, but a matter of law. The rules governing cost reports would not even *allow* one to be filed until long after the Complaint was filed. Relators cannot escape the fact that in their rush to file their specious Complaint, they jumped the gun and tried to base their claim on something that could not yet have occurred. This more than anything explains why the Complaint fails to meet the Rule 9(b) standard: something that hasn't happened cannot be pleaded with particularity.

Moreover, the example given by the Relators to illustrate how a rental arrangement could "otherwise reflect" the volume of referrals supports the Defendants' position that to have an indirect compensation relationship under Stark, there must be some correlation between actual volume and the amount of the rent. Relators conjure a hypothetical situation where a hospital tells a physician "I can't pay you \$50 for each referral, but I expect that you'll refer 10 patients each month, so we'll just agree on a flat fee of \$500 per month." Response at p. 14. While this hypothetical could be said to "otherwise reflect" volume, it is because it is tied directly to volume ($50 \times 10 = 500$). Relators have never alleged that such a direct correlation existed between the rent paid to BRMC under the equipment lease and the referrals of Drs. Saleh and Vaccaro, nor could they, since there is no correlation.

Finally, even if Relators had pleaded that an indirect financial relationship existed between BRMC and Drs. Saleh and Vaccaro, this would not be sufficient to allege a violation of the Stark law. The Stark law does not prohibit any financial relationships. The Stark law only (1) prohibits a physician from making referrals for certain "designated health services" (DHS) payable by Medicare to an entity (such as a hospital) with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare for those referred services, unless an exception applies. 42 U.S.C. §1395nn(a). Accordingly, without the submission of a claim for a service for which payment may not be made by reason of the prohibitions in the Stark law, there can be no violation. Merely alleging the existence of a financial relationship which may not fit a Stark exception is not sufficient. As stated above, Relators have not alleged any specific claims that were submitted by BRMC for designated health services provided to Medicare patients referred by Drs. Saleh or Vaccaro. (Yet

another reason why Relators have failed to comply with Rule 9(b).) Nor have Relators alleged that the lease falls outside any of the applicable exceptions. Therefore, Relators have failed to state a claim for which relief could be granted under the False Claims Act based on an alleged Stark law violation.

3. Relators Should Not Be Allowed to Amend

Notwithstanding the arguments in their Response, Relators should not be allowed to amend their Complaint for the simple reason that the Complaint is based on a cost report that could never have been filed prior to the Complaint being filed. If Relators were now allowed to amend and claim that the cost report has been filed, they would effectively be bootstrapping their way out of the dilemma that their gun-jumping got them into in the first place. If this practice were permitted, anyone could simply conjure up a false claims action out of the supposition that a claim *might* be filed in the future, and then amend once a claim was filed saying "I told you so." Defendants would be unable to defend themselves against such conjectural claims. As the cases cited in Defendants' initial Memorandum make clear, a *qui tam* relator must have a "claim in hand," not one in the bush. Relators in this action have nothing at all. For these reasons, as well as those cited in Defendants'

Motion to Dismiss, their Memorandum in support thereof, and advanced at oral argument (if granted), the Complaint should be dismissed, with prejudice.

Respectfully submitted,

By: /s/Daniel M. Mulholland III
Daniel M. Mulholland III, Esquire
PA I.D. No. 28806
Henry M. Casale, Esquire
PA I.D. No. 42066

HORTY, SPRINGER & MATTERN, P.C.
4614 Fifth Avenue
Pittsburgh, PA 15213
412-687-7677
dmulholland@hortyspringer.com
hcasale@hortyspringer.com

Counsel for Defendant
Bradford Regional Medical Center

Dated: October 18, 2005

By: /s/Jay D. Marinstein
Jay D. Marinstein, Esquire
PA I.D. No. 53163
Carl J. Rychcik, Esquire
PA I.D. No. 73754

FOX ROTHSCHILD LLP
625 Liberty Avenue, 29th Floor
Pittsburgh, PA 15222
(412) 391-1334
jmarinstein@foxrothschild.com
crychcik@foxrothschild.com

Counsel for Defendants,
V & S Medical Associates, LLC,
Peter Vaccaro, M.D. and
Kamran Saleh, M.D.

Dated: October 18, 2005

CERTIFICATE OF SERVICE

I hereby certify that a copy of the attached document was filed electronically with the United States District Court for the Western District of Pennsylvania and also served on each of the following attorneys via First Class United States Mail on the date set forth below:

Andrew M. Stone, Esquire
Stone & Stone
828 Frick Building
437 Grant Street
Pittsburgh, PA 15219

G. Mark Simpson, Esquire
Bothwell & Simpson
304 Macy Drive
Roswell, GA 30076

Robert L. Eberhart, Esquire
United States Attorney's Office
Civil Division
USPO & Courthouse
Pittsburgh, PA 15219

Michael Granston, Esquire
U.S. Department of Justice
Commercial Litigation Branch
P.O. Box 261
Ben Franklin Station
Washington, DC 20044

October 18, 2005

/s/Jay D. Marinstein